#16

Hill, New Providence, NJ 07974, has filed an application requesting approval for the export of the drug ENLON® (edrophonium chloride injection, USP) to Canada and Switzerland. This drug is recommended as a reversal agent or antagonist of nondepolarizing muscle relaxants (neuromuscular blocking agents) such as tubocurarine, atracurium, vecuronium, metocurine or pancuronium, and as adjunctive therapy in the treatment of respiratory depression caused by curare overdosage. The application was received and filed in the Center for Drug Evaluation and Research on April 8, 1988, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 2, 1988, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802, Pub. L. 99–660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 13, 1988.

Daniel L. Michels,

Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 88–8834 Filed 4–21–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88E–0132]

Determination of Regulatory Review Period for Purposes of Patent Extension; Novantrone®

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Novantrone® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Novantrone® (mitoxantrone hydrochloride) which, in combination with other approved drugs, is indicated in the initial therapy of acute nonlymphocytic leukemia in adults. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for Novantrone® from American Cyanamid Co. (U.S. Patent Nos. 4,278,689 and 4,197,249) and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated March 7, 1988, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period and that the active ingredient, mitoxantrone hydrochloride, represented the first permitted commercial marketing or use of that active ingredient. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period. A regulatory review period determination for the product under U.S. Patent No. 4,278,689 was published in the **Federal Register** on March 30, 1988 (53 FR 10291). This notice of regulatory review period determination pertains to the application for U.S. Patent No. 4,197,249 and is essentially identical to the previous notice of regulatory review period determination.

FDA has determined that the applicable regulatory review period for Novantrone® is 3,145 days. Of this time, 1,836 days occurred during the testing phase of the regulatory review period, while 1,309 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 16, 1979. The applicant claims April 16, 1979, as the date the investigational new drug application (IND) for the drug became effective. However, FDA records indicate that the IND was received on April 16, 1979, and pursuant to FDA regulations, became effective on May 16, 1979.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* May 24, 1984. The applicant claims that a new drug application for Novantrone® (NDA 19–297) was initially submitted on May 18, 1984. However, FDA did not receive the application until May 24, 1984.

3. *The date the application was approved:* December 23, 1987. FDA has verified the applicant's claim that NDA 19–297 was approved on December 23, 1987.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 21, 1988, submit to the

Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 19, 1988, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 1988.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 88–8866 Filed 4–21–88; 8:45 am]

BILLING CODE 4160–01–M

Consumer Participation: Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meeting: San Francisco District Office, chaired by Ronald M. Johnson, District Director. The topic to be discussed is the new drug approval process.

DATE: Friday, May 6, 1988; 10 a.m. to 12 m.

ADDRESS: Clemens Room, Clark County Health Department, 625 Shadow Lane, Las Vegas, NV 89127.

FOR FURTHER INFORMATION CONTRACT: Janet McDonald, Consumer Affairs Officer, Food and Drug Administration, 50 United Nations Plaza, Rm. 524, San Francisco, CA 94102, 415–556–1457.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationship between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: April 15, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–8867 File 4–21–88; 8:45 am]

BILLING CODE 4160–01–M

Health Resources and Services Administration

"Low Income Levels" for Health Careers Opportunity Program, Financial Assistance for Disadvantaged Health Professions Students, Nursing Special Project Grants, and Area Health Education Centers

This Notice updates the income levels that are used to define a "low income family" for the support of training for individuals from disadvantaged backgrounds as provided for under section 787, Health Careers Opportunity Program, and the program of Financial Assistance for Disadvantaged Health Professions Students, section 820, Nursing Special Project Grants, and section 781, Area Health Education Centers of the Public Health Service Act as amended.

Sections 57.1804(b)(2) and 57.1905(b)(2) of the progam regulations (42 CFR Part 57, Subparts S and T) require that the Secretary publish periodically in the Federal Register the low income levels which will be used for Public Health Service grants to institutions which provide training for individuals from disadvantaged backgrounds.

The Health Professions Training Assistance Act of 1985, enacted on October 22, 1985, amended section 787 to include stipends under subsections (a)(2)(F) and (b) to individuals from disadvantaged backgrounds and of exceptional financial need (as defined by regulations issued by the Secretary under section 758), who are students at schools of medicine, osteopathy or dentistry.

The income figures below were taken from low income levels, published by the U.S. Bureau of the Census, using an index adopted by a Federal Interagency committee for use in a variety of Federal Programs, then mutiplied by a factor of 1.3 for adaptation to health professions grant programs for which training for individuals from disadvantaged backgrounds is supported. The income figures have been updated to reflect increases in the Consumer Price Index through December 31, 1987.

Size of parents family [1]	Income level [2]
1	$7,600
2	9,900
3	11,800
4	15,100
5	17,800
6 or more	20,000

[1] Includes only dependents listed on Federal income tax forms.

[2] Rounded to $100. Adjusted gross income for calendar year 1987.

Dated: April 18, 1988.

David N. Sundwall,

Administrator, Assistant Surgeon General.

[FR Doc. 88–8868 Filed 4–21–88; 8:45 am]

BILLING CODE 4160–15–M

Public Health Service

Announcement of Availability of Grants for General Family Planning Training Projects

AGENCY: Office of Family Planning, PHS, HHS.

ACTION: Notice.

SUMMARY: The Office of Population Affairs, Office of Family Planning requests applications for grants under the Family Planning Service Training Program authorized under section 1003 of the Public Health Service (PHS) Act [42 U.S.C. 300a–1(a)]. Funds are available to train family planning personnel in order to maintain the high level of performance of family planning service projects.

The Office of Family Planning (OFP) administers Title X of the Public Health Service Act which provides funds for a general training center in each of the ten DHHS regions. The regional training centers provide training to enable service grantees to improve the delivery of family planning services to persons from low-income families and other persons desiring such services.

ADDRESS: Application kits may be obtained from and applications must be submitted to: Grants Management Office, Office of Population Affairs, Room 736E, H.H.H. Building, 200 Independence Avenue SW., Washington, DC 20201.

DATE: Applications must be postmarked or received at the above address no later than close of business June 21, 1988. Private metered postmarks will not be acceptable as proof of timely mailing. Applications which are postmarked or delivered to the Grants Management Office later than June 21, 1988, will be judged late and will not be accepted for review. Applications which do not conform to the requirements of this